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APPLICATION-NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,034	05/29/2001	Roberto A. Macina	DEX-0207	5629

26259 7590 01/23/2002

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EXAMINER

DAVIS, NATALIE A

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/867,034

Applicant(s)

MACINA ET AL.

Examiner

Natalie A. Davis

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1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1 (a) and (c) and 14 (as it reads on nucleic acids), drawn to a CSG polynucleotide and vaccine, classified in class 536, subclass 23.1.
  - II. Claims 1 (b) and 14 (as it reads on protein), drawn to a CSG comprising, classified in class 530, subclass 350.
  - III. Claims 2-6, drawn to a method of diagnosing, staging, and monitoring staging the presence and metastasis of colon cancer, classified in class 435, subclass 4.
  - IV. Claims 7, drawn to a method of identifying potential therapeutic agents, classified in class 435, subclass 4.
  - V. Claim 8, drawn to an antibody of claim 1, classified in class 530, subclass 387.9.
  - VI. Claims 9-10, drawn to a method of imaging colon cancer, classified in class 424, subclass 1.49.
  - VII. Claim 11, drawn to a method of treating colon cancer, classified in class 424, subclass 184.1.
  - VIII. Claims 12-13, drawn to a method of inducing an immune response, classified in class 514, subclass 2.
- A. In the event applicant elects Group I, claims 1 (a) and (c) and 14 or Group II, claims 1 (b) and 14, applicant is required to elect a single species of CSG comprising:
  - Species A, drawn to SEQ ID NO: 1
  - Species B, drawn to SEQ ID NO: 2
  - Species C, drawn to SEQ ID NO: 3
  - Species D, drawn to SEQ ID NO: 4
  - Species E, drawn to SEQ ID NO: 5
  - Species F, drawn to SEQ ID NO: 6
  - Species G, drawn to SEQ ID NO: 7
  - Species H, drawn to SEQ ID NO: 8

Species I, drawn to SEQ ID NO: 9  
Species J, drawn to SEQ ID NO: 10  
Species K, drawn to SEQ ID NO: 11  
Species L, drawn to SEQ ID NO: 12  
Species M, drawn to SEQ ID NO: 13  
Species N, drawn to SEQ ID NO: 14  
Species O, drawn to SEQ ID NO: 15  
Species P, drawn to SEQ ID NO: 16  
Species Q, drawn to SEQ ID NO: 17  
Species R, drawn to SEQ ID NO: 18  
Species S, drawn to SEQ ID NO: 19  
Species T, drawn to SEQ ID NO: 20  
Species U, drawn to SEQ ID NO: 21  
Species V, drawn to SEQ ID NO: 22

Species L-V are patentably distinct based on structural and functional differences.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-II and V (products) and III-IV and VI-VIII (methods) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Groups I-II and V may be used for a number of different processes that are very much unrelated. For example, the antibody of Group v may not only be used in the method of Group VIII, but may also be used for immunopurification. Likewise, the protein of Group II may be used for affinity purification of antibodies and the polynucleotides of Group I may be used to make a protein or as a probe or primer.
3. The products of Groups I, II, and V are drawn to structurally and functionally different molecules with different immunological properties, modes of action, and half-life. The products

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may target different receptors, require different adjuvants or pharmaceutically acceptable carriers, and differ in methods of administration, dosage, and dosage regimen.

4. The methods of Groups III-IV and VI-VIII relate to methods but each method differs in method steps, modes of operation, reagents needed and serve different endpoints and effects. For example, a method of treating is different from a method of diagnosis, staging, and monitoring or imaging, as a method of diagnosing requires comparison of CSG levels in a patient with normal human control, staging and monitoring comprises determining increases in CSG levels and imaging comprises administering an antibody.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, divergent subject matter, and require different search strategies, restriction for examination purposes as indicated is proper.

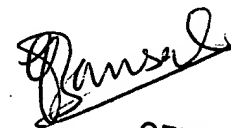
6. Applicant is advised that the response to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, PhD  
January 15, 2002



GEETHA P. BANSAL  
PRIMARY EXAMINER